UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 21-11057-RGS

IN RE AMITIZA ANTITRUST LITIGATION

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTION TO DISMISS

December 27, 2022

STEARNS, D.J.

Plaintiffs FWK Holdings, LLC, Meijer, Inc., Meijer Distribution, Inc., and KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc., bring this antitrust class action against defendants Takeda Pharmaceutical Company Ltd. and Takeda Pharmaceuticals USA, Inc. (Takeda) for alleged violations of Section 1 of the Sherman Act, 15 U.S.C. § 1. Takeda moves to dismiss under Fed. R. Civ. P. 12(b)(6) for failure to state a claim warranting relief. For the following reasons, the court will allow the motion in part.

BACKGROUND

I. Regulatory Framework

The Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act), 21 U.S.C. § 355, is intended to expedite the approval process for the marketing of generic versions of brand-name drugs. A manufacturer desiring to market a generic drug begins the process by filing

an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA). *Id.* § 355(j). If the ANDA establishes a bioequivalence with the brand-name version of the drug, FDA approval will be granted without subjecting the manufacturer to the lengthy and often arduous process of independently proving the generic drug's safety and efficacy. *Id.*; *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013).

Because brand-name drugs are typically protected by patents, the Hatch-Waxman Act requires the aspiring generic manufacturer to demonstrate to the FDA that the proposed generic drug will not infringe any patent listed by the competing brand-name manufacturer in the FDA's "Orange Book." While this can be done in more than one way, as relevant here, the generic manufacturer can simply file a certification claiming that any listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This submission, often termed a "paragraph IV certification," is deemed an infringing act under patent law, and if the brand-name manufacturer responds by filing a lawsuit within 45 days of the date that it receives notice of the certification, any FDA approval of the ANDA is automatically stayed for 30 months while the alleged infringing act is litigated. *Id.* § 355(j)(5)(B)(iii).

As an incentive for the aspiring generic manufacturer to jump into the market, the Hatch-Waxman Act grants a 180-day marketing exclusivity period to the first generic to file a paragraph IV certification. During this marketing exclusivity period, the FDA is barred from approving a competitor's later-filed ANDA. The brand-name manufacturer, however, remains free during this 180-day period to launch a repackaged "authorized generic" (AG) of its own to compete for a share of the market.

II. Factual History

The essential facts, drawn from the Consolidated Amended Class Action Complaint (CAC) (Dkt # 28) and documents incorporated in the CAC by reference, and viewed in the light most favorable to plaintiffs, are as follows.

In 1986, Dr. Ryuji Ueno "identified the therapeutic potential of prostones, a type of chemical derived from prostaglandins, lipid-based compounds that naturally occur in the human body." CAC ¶ 127. Ten years later, he founded Sucampo Pharmaceuticals, Inc. (Sucampo)[1] to develop and market prostone-based drugs. In 1999, Sucampo submitted to the FDA an

[1] Sucampo is not a defendant in this action as its successor, Mallinckrodt plc, filed for bankruptcy in October of 2020.

Investigational New Drug for lubiprostone, the active pharmaceutical compound in Amitiza®.

By the fall of 2004, Sucampo began looking for a partner to boost the effort to commercialize lubiprostone. In October, it entered a marketing agreement with Takeda (the 2004 Takeda-Sucampo Agreement). The agreement gave Takeda a 16-year exclusive license to "co-develop, use, sell, promote, offer for sale, import, and distribute" lubiprostone-based products in the United States in exchange for a negotiated price and, depending on annual net sales, an 18-26% royalty. *Id.* ¶ 144. It also gave Takeda the right to participate in any patent infringement litigation brought by Sucampo, or "to commence patent infringement litigation against generic competitors if Sucampo did not do so." *Id.* ¶ 154.

With Takeda's assistance, Sucampo submitted a New Drug Application (NDA) for Amitiza on March 31, 2005. Although only Sucampo's name was listed on the NDA, Takeda was "integral to all Amitiza-related business and legal decisions" and discussed "every step" of the NDA approval process with Sucampo. *Id.* ¶¶ 153, 156; *see also id.* ¶ 146 ("Sucampo and Takeda also established a joint development committee to focus on clinical development of lubiprostone, including getting regulatory approvals. . . . It, too, operated by unanimous consensus."). The FDA approved Amitiza for the treatment of

chronic idiopathic constipation on January 31, 2006,[2] and Takeda began selling the drug in the United States in April of 2006.

In February of 2010, Anchen Pharmaceuticals, Inc., a predecessor to Par Pharmaceutical, Inc. (collectively, Par),[3] submitted an ANDA to the FDA, seeking approval to market a generic version of Amitiza. After some back-and-forth regarding bioequivalence and additional clinical studies, the FDA accepted Par's ANDA in June of 2012. On December 26, 2012, Par presented Sucampo with a paragraph IV certification. Takeda and Sucampo responded by filing suit in the U.S. District Court for the District of Delaware, triggering the 30-month stay of any FDA approval of Par's ANDA until July 2, 2015. The parties eventually settled the dispute in September of 2014.

Under the terms of the 2014 Settlement Agreement, Par "agreed to delay launching a generic version of Takeda's Amitiza until January 1, 2021," at which point it could sell either its own generic product or Sucampo-supplied AG product. *Id.* ¶ 209. Takeda and Sucampo, in turn, agreed to

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[2] Amitiza is now also approved to treat irritable bowel syndrome in women and opioid-induced constipation in patients with chronic, non-cancer pain. It works by increasing fluid secretion within the intestine. The presence of more water within the intestine softens stool and improves motility, thereby making defecation easier.

[3] Although Par was originally a defendant in this action, plaintiffs voluntarily dismissed their claims against it after Par filed for bankruptcy in August of 2022.

"keep[] other generics out of the market for as long as they possibly could," and to structure the royalty for sales of the Par generic in such a way that, according to plaintiffs, would effectively "ensure[] that there would only be a single generic" available in the market. *Id.* ¶¶ 209, 214. Although Sucampo and Takeda nominally retained the right to launch a competing AG product, the 2014 Settlement Agreement provided for the royalty on sales of the Par generic to decrease so significantly (from 50% to 15%) that Sucampo had no incentive to sell an AG through Takeda.

Par began sales of its generic product on January 4, 2021. It elected the option of selling Sucampo-supplied AG product as opposed to its own generic, which was still waiting FDA approval.

III. The Present Litigation

Plaintiffs are purchasers and assignees of purchasers of Amitiza-branded and AG products. They contend that, but for the 2014 Settlement Agreement, "there would have been at least two generics in the market as early as July 17, 2015, Par's ANDA product and Takeda's authorized generic, with [another] generic entry likely to follow." *Id.* ¶ 4. They filed the instant class action lawsuit seeking to recover the amount they allegedly overpaid for Amitiza-branded and AG products because of the 2014 Settlement

Agreement. The CAC sets out a single count for alleged unreasonable restraint of trade in violation of Section 1 of the Sherman Act.[4]

DISCUSSION

I. Motion to Dismiss

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Two basic principles guide the court's analysis. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679. A claim is facially plausible if its factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678.

A. Standing

Takeda first challenges whether plaintiffs have standing to bring this lawsuit. It argues that the claimed antitrust injury "is based solely on speculation" that the FDA "would have approved the Par ANDA on July 17,

[4] While the original Complaint included a second count for alleged monopolization of the lubiprostone market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, this count is not pled in the CAC.

2015" had the 2014 Settlement Agreement not intervened, an "implausible" hypothesis given the fact that the FDA did not approve the Par ANDA until after January 1, 2021. Mem. in Supp. of its Mot. to Dismiss (Mot. to Dismiss) (Dkt # 43) at 12-13.

The court declines to dismiss on standing grounds. Plaintiffs allege that Par "was not motivated to pursue its own ANDA" despite the approaching deadline for statutory exclusivity eligibility, because the generous terms of the 2014 Settlement Agreement gave it unrestricted access to the Amitiza patents both "with the option to launch an AG" and with contractual exclusivity in the generic market.[5] CAC ¶ 240 & n.72. Plaintiffs also allege that Par "would have reported its license to the FDA," which would have undercut the FDA's motivation to review Par's ANDA with any alacrity, given the FDA's stated focus on giving priority to the ANDAs most likely to bring generic drugs to market as quickly as possible. *Id.* ¶ 240 n.72. Plaintiffs, in other words, have made out a coherent theory of "wink and wait" to explain the parties' lackadaisical approach toward the FDA approval process. These allegations suffice to create a factual inference of a link

[5] Although Takeda argues that Par was "incentivized to obtain ANDA approval to take advantage of a potential earlier launch date," Reply (Dkt # 50) at 5, the court must resolve all factual disputes in plaintiffs' favor at this stage of the litigation.

between the FDA's delay in approving the Par ANDA and the 2014 Settlement Agreement sufficient to defeat a motion to dismiss.[6]

B. Party Status

Takeda next argues that dismissal is warranted because plaintiffs' claim "is based solely on their assertion that the [2014 Settlement Agreement's] royalty structure created economic disincentives that made it less profitable" to launch an AG, and under the 2014 Settlement Agreement, Sucampo – and not Takeda – is contractually owed royalty payments. Mot. to Dismiss at 13. In this regard, Takeda misconstrues the nature of the claim against it. At heart, plaintiffs contend that "Takeda paid Par substantial consideration in exchange for Par's agreement to delay bringing its generic version of Amitiza to the market." CAC ¶ 335. That consideration included agreeing to a below-market royalty rate (in Takeda's case, apparently 0%) and to abstain from launching a competing AG.[7] That Takeda did not itself

[6] *In re Asacol Antitrust Litig.*, 2016 WL 4083333 (D. Mass. July 20, 2016), and *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570 (D. Mass. Sept. 16, 2015), do not compel a contrary conclusion. Unlike the situation here, in neither of those cases did plaintiffs put forward allegations plausibly linking the FDA's failure to approve the relevant ANDAs to the parties' settlement agreements.

[7] At the very least, the court can reasonably infer that, by agreeing to the settlement that allowed the alleged monopoly to operate, Takeda tacitly embraced the implicit *de facto* no-AG condition. Takeda was a party to the infringement suit against Par and consented to drop its claims on terms that

receive any royalty payments does not mean it did not benefit from the 2014 Settlement Agreement or knowingly participate in the alleged implicit reverse payment to Par in order to obtain that benefit. The court accordingly declines to dismiss on this ground as well.

C. Reverse Payment

Takeda next moves to dismiss on the grounds that the 2014 Settlement Agreement is not a reverse payment agreement because it "provides only for payment from Par, an alleged infringer, to Sucampo, the patentee." Mot. to Dismiss at 18. Again, Takeda misconstrues the nature of the claim against it. Plaintiffs allege that Takeda paid Par for an additional five-year period of market exclusivity by providing Par with a below-market royalty payment and implicitly allowing it to have a monopoly in the generic market. The "reverse payment" in this schema is the alleged large and unjustified profits Par received from its monopoly in the generic market and discounted royalty fees. The court is not prepared to say, at this early stage in the litigation, that

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it knew would prevent it from launching an AG product. Plaintiffs, moreover, also allege that, under the terms of the 2004 Takeda-Sucampo Agreement, Takeda (1) was an integral player in all decisions implicating Amitiza; (2) had a right to make recommendations to Sucampo on litigation strategy; and (3) held a 16-year exclusive license to the lubiprostone-based products (which, as Takeda appears to concede, *see* Reply at 8, would render its approval necessary for the grant of a license to Par because the contract contemplates a possible license effective date prior to the expiration of Takeda's exclusive license).

these alleged profits do not qualify as a reverse payment within the scope of Section 1 of the Sherman Act. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 42 (1st Cir. 2016) ("'[N]o-AG' provisions—in which the brand-name manufacturer agrees not to market an 'authorized generic' version of the drug for a certain period of time—and other settlement provisions in which some advantage is transferred from the patent holder to the alleged infringer may constitute a reverse payment subject to antitrust scrutiny."); *Picone v. Shire PLC*, 2017 WL 4873506, at *10-11 (D. Mass. Oct. 20, 2017) (allowing a claim premised on an implicit no-AG agreement to survive a motion to dismiss). So here, too, a dismissal would be premature and potentially unfounded.

D. Generic Sales

Lastly, Takeda invokes *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), arguing that plaintiffs lack standing to recover any damages tied to the sale of Par's AG product. Takeda stands on firmer ground here. As plaintiffs concede in their oppositional briefing, decisions of the First Circuit and district courts within it "establish a rule . . . that so long as the selling member of the alleged antitrust conspiracy (here, Par as to the AG product) is joined as a defendant, the first purchaser outside of the conspiracy has direct-purchaser standing." Opp'n to Mot. to Dismiss (Dkt # 49) at 37. Because

plaintiffs have dismissed their claims against Par, the "selling member of the alleged antitrust conspiracy" is no longer a defendant in the action, thereby eliminating *Illinois Brick* standing. The court accordingly allows so much of Takeda's motion as is premised on generic sales.

II. Motion to Strike

Takeda alternatively moves to strike any allegations in the CAC related to Sucampo's 2015 citizen petition filing under Fed. R. Civ. P. 12(f).[8] The court denies the motion. Motions to strike are generally disfavored, *see, e.g.*, *Manning v. Bos. Med. Ctr. Corp.*, 725 F.3d 34, 59 (1st Cir. 2013), and the court is not prepared at this juncture to say that the challenged allegations are immaterial to any conspiracy or anticompetitive intent Sucampo and Takeda may have had during the relevant time period.

ORDER

For the foregoing reasons, Takeda's Motion to Dismiss is DENIED IN PART and ALLOWED IN PART.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE

[8] The motion to dismiss any claims premised on these allegations is denied as moot. Plaintiffs do not assert any substantive claim based on them.